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09/960,471	09/19/2001	Francois Mach	23135-501 CIP (NOV-1 CIP)	6761

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EXAMINER

WANG, SHENGJUN

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 05/20/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/960,471

Applicant(s)

MACH, FRANCOIS

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-6, 11, 12, 16-21, 21-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) 29, 30 and 93 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-6, 11, 12 and 16-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6. 6) ☐ Other: _____

DETAILED ACTION

1. Claims 29, 30, and 93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

1. Applicant's election with traverse of invention group III, claims 4, 5-7, 10, 11, 16-26 (in part) and claim 12 in Paper No. 10 is acknowledged. The traversal is on the ground(s) that invention groups III, VI, IX, XI and XX are all related to CD40 mediated immuno-inflammation. This is not found persuasive because the inventions herein listed are patentable distinct as discussed in the prior office action. The searches of each and every inventions herein are required even with the alleged linkage. Further, the alleged linkage will not change the fact that the inventions are distinct from each other, particularly, the inventions herein differ with respect to ingredients, method steps and final results. They therefore have different issues regarding patentability and enablement and represent patentable distinct subject matter.

The requirement is still deemed proper and is therefore made FINAL.

The claims have been examined insofar as they read on the elected invention.

Double Patenting Rejections

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1617

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 4-6, 11, 12, 16-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, 15-20, and 35-37 of copending Application No. 09/664,871; claims 94-103 of copending Application No. 10/056,645; claims 94-105 of copending Application No. 10/056,646; claims 94-103 of copending Application No. 10/056,608; Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to the claims in the copending applications. Note, all the claims are drawn to method for treating the same disorders with the same compounds, and differ from each other only in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections 35 U.S.C. 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 4-6, 11-12, 16, 17, 19-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the particular statins listed in claim 18, does not reasonably provide enablement for "a functionally or structurally equivalent molecule, (optionally, "has no lipid-lowering effect," claim 20)" of statin (claim 4). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Applicant

Art Unit: 1617

uses functional limitation “a functionally or structurally equivalent molecule, (optionally, “has no lipid-lowering effect,” claim 20)” of statin to defined the agents employed in the method, but fails to provide sufficient guidance, direction, or working examples as to how to make and use such “a functionally or structurally equivalent molecule,” of statin. A person of ordinary skill in the art would have been required to perform undue experimentation to use claimed invention, particularly, to identify those “a functionally or structurally equivalent molecule, (optionally, “has no lipid-lowering effect,” claim 20)” of statin within claimed scope. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ 2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factor to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The claim recites the employment of “a functionally or structurally equivalent molecule,” of statin. There is no known or disclosed co-relationship between chemical structure of the

Art Unit: 1617

compounds and the recited properties, i.e., “a functionally or structurally equivalent” Applicants fail to provide information allowing skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of statins are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed of physiological activity. The instant claims read on all compounds which are “functionally or structurally equivalent molecule, (optionally, “has no lipid-lowering effect,” claim 20)” of statin, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention, absent undue experimentation.

Claim Rejections 35 U.S.C. 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 4-5, 11, 12, 16-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Partridge (US 6,403,637).

4. Partridge teaches a method of treating arthritis, including rheumatoid arthritis, comprising administering to the patient a statin compound, such as atorvastatin. See, particularly, column 6,

Art Unit: 1617

lines 17-21, and the claims. As to the particular function herein recited, "to achieve CD40-mediated anti immuno-inflammatory effect", applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA 1993) illustrating anticipation resulting from inherent use, absent a *haec verba* recitation for such utility. In the instant application, as in *Ex parte Novitski*, supra, the claims are directed to treating or preventing a malady or disease with old and well-known compounds or compositions. It is now well-settled law that administering compounds inherently possessing a therapeutic utility anticipates claims directed to such therapeutic use. Arguments that such therapeutic use is not set forth *haec verba* are not probative. Prior use for the same utility clearly anticipates such utility, absent limitations distancing the proffered claims from the inherent anticipated use. Attempts to distance claims from anticipated utilities with specification limitations will not be successful. At page 1391, *Ex parte Novitski*, supra, the Board said "We are mindful that, during the patent examination, pending claims must be interpreted as broadly as their terms reasonably allow. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). As often stated by the CCPA, "we will not read into claims in pending applications limitations from the specification." *In re Winkhaus*, 52 F.2d 637, 188 USPQ 219 (CCPA 1975)". In the instant application, Applicants' failure to distance the proffered claims from the anticipated therapeutic utility, renders such claims anticipated by the prior inherent use.

Claim Rejections 35 U.S.C. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4-6, 11, 12, and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partridge (US 6,403,637).

7. Partridge teaches a method of treating arthritis, including rheumatoid arthritis, comprising administering to the patient a statin compound, such as atorvastatin. See, particularly, column 6, lines 17-21, and the claims.

8. Partridge does not teach expressly the treatment of rheumatoid arthritis, or the particular dosage and administration method herein.

1. However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Partridge's method for treating rheumatoid arthritis because Partridge discloses that the method is useful for arthritis which comprises rheumatoid arthritis. Further, the optimization of a result effective parameter, e.g., effective dosage, or method of administration, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. The instant claims are directed to affecting a biochemical pathway with an old and well known compounds. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan.

Art Unit: 1617

2. Claims 4-6, 11, 12, and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisgaier et al. (WO 99/30706) in view of Merck Manual.

3. Bisgaier et al. teach a method of treating arteriosclerosis comprising administering the patient a statin compound, such as atorvastatin. See, particularly, the claims. Bisgaier et al. also discloses that it is a common practice in the art to administer statins to a subject for prophylactic treatments. See, particularly, page 1, lines 15-25.

4. Bisgaier et al. does not teach expressly to employ the method for treating diabetes patient.

5. However, Merck Manual shows that diabetes patients, particularly insulin-dependent diabetes patients tend to develop hyperglycemia and arteriosclerosis. See particularly, page 1070.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ Bisgaier's method for treating diabetes patients, even before they have developed hyperglycemia and arteriosclerosis.

6. A person of ordinary skill in the art would have been motivated to employ Bisgaier's method for treating diabetes patients, even before they have developed hyperglycemia and arteriosclerosis because it is well known in the art that diabetes patients tend to develop hyperglycemia and arteriosclerosis, and prophylactic treating of suppressing the development of hyperglycemia and arteriosclerosis are well known. Further, the optimization of a result effective parameter, e.g., effective dosage, or method of administration, is considered within the skill of the artisan. See, In re Boesch and Slaney (CCPA) 204 USPQ 215. The instant claims are directed to affecting a biochemical pathway with an old and well known compounds. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226

Art Unit: 1617

at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Patent Examiner
SHENGJUN WANG
PATENT EXAMINER

Shengjun Wang

May 17, 2003